

## **REMARKS/ARGUMENTS**

### **Restriction**

The Examiner has required restriction of the claims. Applicants confirm the election of Group I, claims 1-12, as made by telephone on April 24, 2006. No amendment of inventorship is necessitated by this election.

### **Rejections under 35 USC 112 – Second paragraph**

Claim 10 has been rejected as failing to comply with the second paragraph of 35 USC 112.

Claim 10 has been amended and the rejection is obviated.

### **Rejections under 35 USC 112 – Written description**

Claims 1-12 have been rejected as failing to comply with the written description requirement. The Examiner has held that SEQ ID NO: 1 does not constitute description of a representative number of claimed molecules and that insufficient guidance was provided by the Applicants about what structures are required for promoter activity. Applicants respectfully traverse the rejection.

While not conceding any deficiency in written description for the claims as originally filed, in an effort to advance prosecution, Applicants have amended the claims to comprise an isolated nucleic acid molecule comprising a polynucleotide which initiates transcription in a plant cell and comprises a sequence having at least 90% sequence identity to SEQ ID NO: 1, wherein the % sequence identity is based on the entire length of SEQ ID NO: 1.

The test for adequate written description is “whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.” *In re*

*Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (citations omitted). More recently, and with respect to the biotechnological arts, the Court of Appeals for the Federal Circuit has held that “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met.” *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

In the present case, a full-length promoter sequence is provided. Methods and outcomes of modification of this sequence are described in the specification, for example from page 12, line 12, through page 15, line 12.

As stated in the USPTO Guidelines published January 5, 2001 (Federal Register 66(4):1099-1111, including Comments; hereinafter “Guidelines”), at p. 1101, the level of skill in the art is a consideration relevant to the written description requirement, and “the disclosure taken with the knowledge of those skilled in the art may be sufficient support for the claims.” (citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985); emphasis added) It would be well within the purview of one of skill in the art to make modifications to SEQ ID NO: 1 as described in the specification and to test such modified sequences for functional promoter activity as also described in the specification.

“An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” Guidelines p. 1106.

In the present case, the Applicants have provided at least the following:

the complete polynucleotide sequence of the full-length invertase inhibitor promoter (SEQ ID NO: 1); and functional characteristics coupled with a known or

disclosed correlation between function and structure (Figure 1, indication of tissue-specificity; page 14, lines 1-24, discussion of structural motifs affecting promoter function).

The combination of these characteristics, taken together with the knowledge of one of skill in the art, for example the promoter assay methods referenced at page 16, line 18, through page 17, line 4, provides adequate written description for the claims as amended.

In light of the amendments and arguments presented herein, Applicants respectfully ask that all rejections for lack of written description be withdrawn.

#### Rejections under 35 USC 112 – Enablement

The Examiner has rejected Claims 1-12 as not enabling.

The Applicants respectfully traverse the rejection.

Claim 1 has been amended to specify 90% identity. Claims 2-12 depend from Claim 1.

With respect to whether the application is enabled as to promoter functionality of SEQ ID NO: 1, Applicants point out that “[n]othing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993)

The Examiner has cited Kim et al. (1994) “who teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco.” Specific mutations were reported as resulting in explicit fold-changes in promoter activity.

The Applicants respectfully assert that the detailed analysis of Kim et al., conducted almost ten years prior to the effective filing date of the present application, is evidence that evaluation of promoter function via mutation and expression analysis was, at the time of filing, routine and well within the skill of those

in the art. “The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.” *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 68 USPQ2d 1280 (Fed. Cir. 2003).

The Examiner states that one of skill in the art would be required “to randomly produce an endless number of substitutions and deletions from SEQ ID NO: 1, which is undue experimentation.”

Applicants respectfully assert that a requirement for testing is not in itself sufficient grounds for a finding of non-enablement. It is well established that “determination of whether the requisite amount of experimentation is undue may include consideration of: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Further, the Court held, “[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” (*Id.*, quoting *Ex parte Jackson*, 217 USPQ 804, 817 (Bd. App. 1982).

That guidance is provided, in the identified elements (e.g. at page 14 of the specification) and the boundary of 90% identity as now set forth in the claims.

In light of the amendments and arguments presented herein, Applicants respectfully ask that all rejections for lack of enablement be withdrawn.

#### Rejections under 35 USC 102 - Anticipation

The Examiner has rejected Claim 1 as anticipated by Bonello et al. (Gene (2000) 246:219-227), asserting that the ESR promoters taught by Bonello “have the

inherent characteristic of being able to hybridize to the complement of SEQ ID NO: 1 under conditions of some stringency.”

The Applicants respectfully traverse the rejection. A BESTFIT analysis of each of the ESR1, ESR2, and ESR3 promoters of the cited reference indicates no meaningful shared identity which would result in hybridization. (See Appendix for sequence alignments.) Nevertheless, in an effort to expedite prosecution, Applicants have amended the hybridization conditions of Claim 1 to reflect those described as “high stringency” in the specification at page 19.

The Examiner has rejected Claims 1-12 as anticipated by Chaudhary et al. (WO 01/16340).

The Applicants respectfully traverse the rejection. A BESTFIT analysis of each of the four promoter sequences disclosed by Chaudhary et al. indicates no meaningful shared identity which would result in hybridization. (See Appendix for sequence alignments; corresponding sequences from U.S. 6,777,591 (Chaudhary) are shown.) Nevertheless, in an effort to expedite prosecution, Applicants have amended the hybridization conditions of Claim 1 to reflect those described as “high stringency” in the specification at page 19.

In light of the amendments and arguments presented herein, Applicants respectfully ask that all rejections for anticipation be withdrawn.

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For all the reasons presented above, it is believed that the claims are now in condition for allowance, and early notice to this effect is requested. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the above-referenced application, the Examiner is invited to call the undersigned.

Respectfully submitted,

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